

Pharmaceutical Regulatory Affairs 2012: Effective regulatory information management - Reliance Life Sciences, India

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Abstract

Regulatory departments are continually being asked to do more with less. In addition, regulatory authorities are increasing the scrutiny related to patient safety and compliance. As regulatory departments are challenged to develop both domestic and global regulatory strategies, coupled with the corporate desire to launch in products in the markets early, the need to understand the regulatory requirements for filing, timelines, what products are approved in which markets is becoming a critical regulatory need for both industry and regulators. Effective regulatory information management processes with appropriate tools are needed to ensure the organization remains compliant with its product registrations. CamBioTec, a Canadian-Latin American Network promoting the safe and effective use of agricultural and environmental biotechnology, undertook an analysis of the current capacities of Argentina, Chile and Canada with respect to the management of information related to assessment and approval of products of modern biotechnology/ genetically engineering.

This report is based on data obtained during a number of interviews and institutional visits conducted during August 1998 and includes: an overview of current regulatory policy, identification of key human resources and authorities, analysis of information management capacity, recommendations for capacity building, and descriptions of relevant international initiatives.

Canada has a regulatory system in place that is respected throughout the world for its ability to insure high-quality agricultural biotechnology products that meet international human and environmental health and safety standards. Argentina is recognized as leader among Latin American countries in the regulation of biotechnology products. Chile is a well-known center of genetic diversity for a number of plant species but with very little in the way of biosafety regulation. Together these countries represent a broad spectrum of technical experience, regulatory policy, and agricultural interests. Participation in social sensing applications is challenged by privacy threats. Large-scale access to citizens' data allow surveillance and discriminatory actions that may result in segregation phenomena in society. On the contrary are the benefits of accurate computing analytics required for more informed decision-making, more effective policies and regulation of techno-socio-economic systems supported by 'Internet-of Things' technologies. In contrast to

earlier work that either focuses on privacy protection or Big Data analytics, this paper proposes a self-regulatory information sharing system that bridges this gap. This is achieved by modeling information sharing as a supply-demand system run by computational markets. On the supply side lie the citizens that make incentivized but self-determined decisions about the level of information they share. On the demand side stand data aggregators that provide rewards to citizens to receive the required data for accurate analytics. The system is empirically evaluated with two real-world datasets from two application domains: (i) Smart Grids and (ii) mobile phone sensing. Experimental results quantify trade-offs between privacy-preservation, accuracy of analytics and costs from the provided rewards under different experimental settings. Findings show a higher privacy-preservation that depends on the number of participating citizens and the type of data summarized. Moreover, analytics with summarization data tolerate high local errors without a significant influence on the global accuracy. In other words, local errors cancel out. Rewards can be optimized to be fair so that citizens with more significant sharing of information receive higher rewards. All these findings motivate a new paradigm of truly decentralized and ethical data analytics.